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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,873	01/18/2002	Steven M. Ruben	PZ029P2	6536

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,873	RUBEN ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,13,17-21 and 24-45* is/are pending in the application.

4a) Of the above claim(s) *1,13,17-21 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 25-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9/22/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 2-10, 14-16, 22-23 and adding new claims 25-45, filed on 22 September 2003 is acknowledged.

Thus claims 1, 11, 13, 17-21, 24 and 25-45 are pending and under consideration.

Election/Restriction:

2. Applicant's election with traverse of the invention of Group II (claims 11 and new claims 25-45), drawn to an isolated polypeptide, is acknowledged. The traversal is on the grounds that the Examiner has not shown that examination of Groups I-VII would entail a serious burden. Applicants submit that a search of the claims of any of the groups would provide useful information for the claims of the other groups. Therefore, since the searches for proteins, nucleic acids encoding said proteins and antibodies to said proteins commonly overlap, the combined search and examination would not entail a serious burden.

Applicant reserves the right to file divisional applications to the presently non-elected subject matter and the right to petition from the restriction requirement.

This traversal has been fully considered but is not deemed persuasive. The inventions of Groups I-VII are drawn to patentably distinct inventions and are classified in different classes and sub-classes and each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search, (MPEP § 808.02). Also, contrary to Applicants' assertion a single search would not reveal art pertinent to all of the claimed inventions. Thus, searching and examining more than one product would pose an undue burden on the Examiner.

Applicants' reservation of the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the remaining claims is noted. Applicant's right to file a Petition under 37 CFR 1.144, to appeal the restriction requirement, is also acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

The elected invention is Group II (claims 11 and 25-45). Therefore, claims 1, 13, 17-21, 24 are withdrawn from prosecution as being drawn to a non-elected invention.

Information Disclosure Statement:

3a. References AF, AG, AH, AI, AJ, AK, AL, AM, AN and AO, cited on the PTO-1449 form submitted by Applicants on 22 September 2003, have not been considered, because these references do not comply with 37 CFR 1.98. 37 CFR 1.98(a)(2) requirements. These references fail to identify each publication by author. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification:

4a. Instant application contains Figures 1A, 1B and 1C, however, the specification lacks a section describing these figures. The specification must have a section entitled "Brief Description of the Drawings" that describes these figures. Appropriate correction is required.

4b. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim objections:

5. Claims 11 and 29 are objected to because of the following informalities: Claim 11 is objected to, because it recites SEQ ID NOs: X and Y. Table 1, on page 265 of the instant specification discloses that these SEQ ID NOs: encompass close to 200 disparate sequences. Claim 29 is objected to because it recites "the amino acid sequence (f)". Claim 25 is a Markush claim which has sub-parts a, b and c. Appropriate correction is required.

What needs to be done to fix problem?

Claim Rejections - 35 U.S.C. § 101/112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6a. Claims 11 and 25-45 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 11 and 25-45 of the instant invention are directed to an isolated polypeptide of SEQ ID NO:222. The specification designates the polypeptide of SEQ ID NO:222, (see figure 14). Instant specification discloses that the polypeptide of SEQ ID NO:222 comprises 522 amino acid residues. The specification describes the translation

product of GENE NO 89 as having sequence homology with the human CGI-06 protein, (see page 243, lines 28-30). However, the instant specification does not disclose an activity for the claimed polypeptide, neither does it disclose the physiological relevance of this polypeptide. The fact that the translation product of GENE NO:89 shares homology with human CGI-06 protein does not assure that the claimed polypeptide has the same function and physiological relevance as human CGI-06 protein. The specification also discloses that supernatants removed from cells containing this gene activated gamma activation site, when tested against the myeloid cell line, U937. The instant specification speculates that "it is likely that this gene activates myeloid cells through the Jaks-STAT signal transduction", (top of page 244). However, the ability to activate gamma activation site or the ability to activate cells through the Jaks-STAT signal transduction, does not impart a utility common to all proteins that activate this pathway. The instant specification also discloses that the gene of the instant invention is expressed in various tumors, including endometrial tumors, adenocacrcinoma, breast cancer, (page 244, lines 13-15), however, the specification does not show the significance of this expression, or whether this gene is only expressed in tumor tissues and never in healthy tissues. The specification contends that the claimed polypeptide might be useful in treating, detecting and /or preventing hyper-proliferative disorders and may modulate apoptosis or tissue differentiation, (page 245, lines 19-30). However, aside from this mere speculation, instant specification does not provide any evidence that the claimed polypeptide is indeed involved in any of these disorders, and if so, how? Instant specification does not disclose or provide any evidence that points

to an activity for the polypeptide of SEQ ID NO:222 and there is no art of record that discloses or suggests any activity for said polypeptide, therefore, the skilled artisan would not know how to use it.

Thus, there is no specific and substantial or well-established utility for the claimed polypeptide of SEQ ID NO:222. The fact that the translation product of GENE NO:89 shares homology with human CGI-06 protein, is not enough to establish a specific and substantial utility or a well established utility for the polypeptide of SEQ ID NO:222.

6b. Claims 11 and 25-45 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Instant specification only discloses a deduced amino acid sequence for the claimed protein, it never discloses an activity for it, neither does it disclose any disorders involve said protien, there is no mechanism of action proposed for it, therefore the skilled artisan would not know how to use the polypeptide comprising the amino acid set forth in SEQ ID NO:222.

Assuming that SEQ ID NO:Y, recited in claim 11 is SEQ ID NO:222, and assuming that Applicants establish an activity for the polypeptide of SEQ ID NO:222, instant specification would still fail to adequately describe and enable an isolated protein comprising a polypeptide which is at least 95% identical to the polypeptide of SEQ ID NO:222. Applicants do not teach which 5% of said polypeptide to mutate, and if said

mutations are in regions critical to the function of the polypeptide. Thus without information regarding which regions are critical to a specific function, the full scope of the claimed invention is not enabled. In summary, the amount of experimentation required for one of ordinary skill in the art to use the claimed invention, a polypeptide having 95% identity to SEQ ID NO:222, would be undue. In Ex parte Forman, 230 USPQ 546 (Bd. Pat. Appls, and Interf. 1986), the Board considered the issue of enablement in molecular biology. The Board held that the following factors should be considered to determine whether the claimed invention would require of the skilled artisan undue experimentation: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. The level of skill in the art of molecular biology is high, but the nature of the invention is not well characterized (i.e. the polypeptide of SEQ ID NO:222 of the instant invention is novel). Therefore, since the state of the prior art is relatively silent to the invention that is claimed, and since Applicants have not provided an activity for the claimed protein, which regions of the polypeptide are critical for its' function, or any disorders that involve said protein, the skilled artisan would not know how to make and use the claimed polypeptide.

6c. Claims 36-45 are ejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 36-45 are rejected, because the claims are drawn to an isolated polypeptide encoded by the HOGCK20 cDNA contained in ATCC accession number 209853. It is apparent that the cDNA is required to practice the claimed invention. As such said cDNA must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If the cDNA is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of this cDNA.

The specification, provides an ATCC accession number for the claimed cDNA, however, the specification lacks complete deposit information for the deposit of the cDNA. If a deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that (a) during pendency of the application, access to the invention will be afforded to the Commissioner upon request, (b) all restrictions upon availability to the public will be irrevocable removed upon

granting of the patent, © the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer, (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807) and (e) the deposit will be replaced if it should ever become inviable.

Conclusion:

7. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art unit 1647
12 December 2003

Gary L. Kunz
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